multi-center, observational study on GIST patients treated with Imatinib between the availability on the French Market and the end of the 2008. Centers were randomly selected in national files of oncologists, gastrointestinal surgeons and specialists. The planned follow-up duration was three years. A case report form had to be completed at inclusion and during each follow-up visits. Quality of life was assessed using QLQ-C30 and SF36 questionnaires. **RESULTS:** Thirty on 51 selected centers enrolled at least one patient and 139 patients were included (as of June 2009). The median age of disease onset was 58 years (range 21–86). 42% were metastatic at diagnosis. Primary tumors were most often stomach (48%), or bowel (34%). At diagnosis 86% of patients had a tumor size over 5 cm. 68% of patients had surgery of the primary tumor before starting Imatinib. 68% of patients were considered as high risk of relapse according the Miettinen classification. For 99% of the patients, Imatinib was given at an initial dosage of 400 mg, 1% at 300 mg. Compliance was superior to 90% for 99% of patients. With a median follow-up of 2.1 years, two-years overall survival from first treatment with Imatinib was 83.9% (CI95%: [74.5%–90.1%]). **CONCLUSIONS:** EPIGIST is still an ongoing survey. Current results confirm previous published data on survival in GIST treated with Imatinib in an unselected cohort of patients outside of a clinical trial.

PCN11

INDIRECT COMPARISON TO ESTIMATE THE EFFICACY OF INTERVENTIONS IN TREATMENT OF METASTATIC RENAL CELL CARCINOMA: A MIXED TREATMENT COMPARISON

Bonthapally V[1], Ghosh S[2], Rappaport H[3]
[1]University of Louisiana at Monroe, Monroe, LA, USA, [2]Independent, West Monroe, LA, USA, [3]The University of Louisiana at Monroe, Monroe, LA, USA

OBJECTIVES: The purpose of the study was to evaluate the relative efficacy of different medication interventions in the treatment of metastatic renal cell carcinoma (mRCC) using a Bayesian mixed treatment comparison (MTC) model. **METHODS:** A systemic review was undertaken to identify randomized controlled trials assessing the efficacy of bevacizumab, sorafenib, sunitinib, temsirolimus, and everolimus as stand alone therapy or in combination with interferon Alfa. The search was conducted within seven electronic data bases (CinAhl, AMED, Cochrane Library, Embase, Medline, ASCO, and Clinical trials.gov) for English language publications from inception to June 6th 2009. The Progression Free Survival (PFS) was outcome of interest in this study. Bayesian MTC was performed for evidence synthesis using both fixed and random effect models. With MTC, the relative treatment effect of one intervention compared with another can be obtained in the absence of head-to-head evidence. **RESULTS:** Sunitinib yielded an effect size of 0.75 (95% credible interval: 0.61–0.93) compared to bevacizumab+interferon; 0.43 (0.31–0.75) compared to bevacizumab; 0.54 (0.37–0.85) compared to sorafenib; 0.74 (0.57–0.96) compared to temsirolimus; and 0.97 (0.57–1.57) compared to everolimus. **CONCLUSIONS:** The relative efficacy of sunitinib was better than all medication interventions on PFS except everolimus in the treatment of mRCC.

PCN12

EXPLORING THE ROLE OF OUTCOMES RESEARCH IN DUTCH REIMBURSEMENT POLICY: REAL-WORLD PHARMACOECONOMICS OF OXALIPLATIN IN STAGE III COLON CANCER

van Gils CWM[1], Redekop WK[1], Punt CJA[2], Uyl-de Groot CA[1]
[1]Erasmus University Medical Center, Rotterdam, The Netherlands, [2]University Medical Center St Radboud, Nijmegen, The Netherlands

OBJECTIVES: In the Netherlands, additional funding of expensive hospital drugs requires an assessment of real-world cost-effectiveness within 3 years after implementing. We explored the use and limitations of real-world data for the economic evaluation of oxaliplatin plus standard adjuvant treatment in stage III colon cancer. **METHODS:** Real-world data were gathered from the Dutch population-based Cancer Registry supplemented with data from medical records. Patients additionally treated with oxaliplatin (N = 101) were compared to patients receiving only standard adjuvant therapy (N = 105). Moreover, comparisons were made between our findings and results from the randomised controlled trial (RCT) that demonstrated a significantly improved disease-free survival with oxaliplatin, on which current Dutch treatment guidelines are based. **RESULTS:** Patients receiving oxaliplatin are significantly younger and have fewer comorbidities than patients receiving alternative chemotherapy. Median follow-up time of the study was 26.6 months. The adjusted hazard ratio for disease-free survival of 0.84 indicated that oxaliplatin was more effective. However, the 95% confidence interval of 0.35–2.03 revealed large uncertainty about the actual effectiveness in daily clinical practice. Moreover, residual confounding could not be ruled out. On the other hand, patient characteristics, treatment patterns, comparator arm, dosages, toxicities, resource use, costs and disease-free survival outcomes obtained in clinical daily practice showed great similarities with the RCT based data and results. During our study, extended 6-year RCT follow-up results became available which confirmed previous findings. **CONCLUSIONS:** Insight into patient characteristics, treatment patterns, dosage and toxicities observed in daily clinical practice is very useful in determining the extent to which RCT results are generalisable to a real-world setting. However, outcomes research alone does not necessarily lead to internally valid and precise estimates of effectiveness and cost-effectiveness. In these situations, assessment of real-world cost-effectiveness should be based on a careful synthesis of RCT results and real-world observations.

PCN13

A COMPARATIVE EFFECTIVENESS ASSESSMENT OF FIRST-LINE BEVACIZUMAB + INTERFERON ALPHA-2A VS SUNITINIB IN METASTATIC RENAL CELL CARCINOMA

Mickisch GH[1], Schwander B[2], Escudier B[3], Bellmunt J[4], Maroto P[5], Porta C[6], Walzer S[7], Siebert U[8]
[1]Center of Operative Urology Bremen, Bremen, Germany, [2]AiM GmbH Assessment in Medicine, Schopfheim, Germany, [3]Institut Gustave Roussy, Villejuif, France, [4]University Hospital del Mar. UPF, Barcelona, Spain, [5]Hospital de la Santa Creu i Sant Pau, Barcelona, Spain, [6]IRCCS San Matteo University Hospital Foundation, Pavia, Italy, [7]F. Hoffmann-La Roche Pharmaceuticals AG, Basel, Switzerland, [8]UMIT—University for Health Sciences, Medical Informatics and Technology, Hall i.T, Austria

OBJECTIVES: Bevacizumab (BEV) + Interferon-alpha-2a (IFN-α) and sunitinib (SUN) have shown significant increase in progression free survival (PFS) compared to IFN-α in first-line metastatic renal cell carcinoma (mRCC) therapy. There is no head-to-head evidence available comparing both regimens, however there is an increasing need to assess and compare the relative efficacy and effectiveness of both therapy approaches. **METHODS:** We applied the widely accepted indirect comparison method (Bucher et al. *J Clin Epidemiol* 1997) to PFS data of the pivotal phase III trials, that is, the unadjusted investigator-assessed PFS hazard ratios (HR) for BEV+IFN-α vs. IFN-α (0.63) and for SUN vs IFN-α (0.52). To enable valid indirect comparison, the IFN-α control arms of both trials have been standardised by recalculating the indirect HR and transferring them into direct HR estimates using the cross-trial proportions. In addition, we adjusted for effects of down-dosing and patient compliance based on published evidence. Sensitivity analyses on adjustment components have been performed. **RESULTS:** The unadjusted indirect efficacy comparison resulted in a statistically non-significant PFS difference of SUN vs BEV+IFN-α (HR: 0.82; 95% CI: 0.64–1.06; p = 0.13). Standardising the IFN arms and simulating realistic scenarios for SUN down-dosing and patient compliance results in similar PFS HRs for BEV+IFN-α (HR: 0.63) and Sunitinib (HR: 0.64) as compared to IFN alone. The adjusted indirect PFS HR of SUN vs BEV + IFN-α was 1.025 (95% CI: 0.81–1.30; p = 0.83). Results were mostly influenced by IFN-α control arm adjustment, followed by patient compliance and down-dosing. **CONCLUSIONS:** Based on our comparative effectiveness evaluation in first-line mRCC therapy, there is no statistically significant evidence for a difference in efficacy and effectiveness regarding PFS between BEV+IFN-α and SUN. These findings imply that additional treatment decision criteria such as tolerability need to be considered to guide treatment decisions.

PCN14

AN INDIRECT COMPARISON OF THE EFFICACY OF BEVACIZUMAB PLUS CISPLATIN AND GEMCITABINE (BCG) OR BEVACIZUMAB PLUS CARBOPLATIN AND PACLITAXEL (BCP) VERSUS CETUXIMAB PLUS VINORELBINE AND CISPLATIN (CVC) IN PATIENTS WITH ADVANCED OR RECURRENT NON-SQUAMOUS NON-SMALL CELL LUNG CANCER (NSCLC)

Walzer S[1], de Castro Carpeño J[2], Vergnenegre A[3], Chouaid C[4], Heigener D[5], Bischoff HG[6], Aultman R[7], Siebert U[8]
[1]F. Hoffmann-La Roche Pharmaceuticals AG, Basel, Switzerland, [2]Hospital Universitario de La Paz, Madrid, Spain, [3]CHU Limoges, Limoges, France, [4]Hopital saint antoine, Paris, France, [5]Krankenhaus Grosshansdorf, Grosshansdorf, Germany, [6]Thoraxklinik Heidelberg, Heidelberg, Germany, [7]F. Hoffmann-La Roche Ltd, Basel, Switzerland, [8]UMIT—University for Health Sciences, Medical Informatics and Technology, Hall i.T, Austria

OBJECTIVES: New treatment options are needed for advanced NSCLC offering improved progression-free (PFS) and overall survival (OS) over standard chemotherapy. Bevacizumab, a humanised monoclonal antibody (MAb) against VEGF, plus chemotherapy increases PFS and OS in advanced NSCLC patients versus chemotherapy alone[4–5]. Cetuximab, a MAb targeting EGFR, showed significant OS when combined with chemotherapy[3]. This study compared the clinical benefits for NSCLC patients treated with BCG or BCP to CVC using indirect treatment comparison (ITC) methodology. **METHODS:** In the absence of head-to-head trials, ITC[1–2] was performed on patients with non-squamous NSCLC comparing the relative benefit of first-line therapies BCG/BCP versus CVC by hazard ratios (HR) adjusted for differences in underlying chemotherapy and populations. Where HRs were not reported, HRs[1] and standard errors[6] were estimated. Based on the ITC a statistical disease model was developed to estimate the adjusted time in PFS and OS. **RESULTS:** ITC-estimated HRs for the primary endpoints in AVAiL[4] and E4599[5] showed that the adjusted PFS HR for BCG versus CVC was 0.80 resulting in an expected time spent in PFS for BCG of 9.62 versus 7.99 months for CVC. Model-derived data showed BCP treatment in patients with adenocarcinoma histology resulted in adjusted BCP HR of 0.89 versus CVC. Model data also showed that BCP patients experienced on average, 19.55 versus. 17.57 months (CVC) of OS. Sensitivity analyses confirmed the robustness of these findings. **CONCLUSIONS:** Interpretation of ITC findings are limited due to cross-study heterogeneity. However results show that BCG or BCP therapy in patients with advanced non-squamous NSCLC brings a superior benefit in terms of OS and PFS compared with CVC therapy.